

The specification has been amended to comply with the Examiner's suggestions.

The rejection of claims 1, 2, 4, 5, 12 and 13 under 35 USC 101 has been overcome by the newly presented claims which are proper method of use claims.

The rejection of claim 1 under 35 USC 112, first paragraph has been overcome by the newly presented claims and/or is not deemed tenable. In particular, The Metabolic Syndrome, which has also been named Syndrome X, is well known. The major features of it are abdominal/visceral obesity, insulin resistance, hypertension, dyslipoproteinemia and a greatly increased risk of developing type 2 diabetes mellitus (non-insulin dependent diabetes mellitus). Patients suffering therefrom also have markedly increased cardiovascular morbidity and mortality.

Claim 19 recites various symptoms of The Metabolic Syndrome. In addition to showing the effectiveness for treating non-insulin dependent diabetes mellitus, the specification discloses treating various of these other conditions. For instance, the specification discloses the effect on reducing abdominal/visceral obesity, lipoprotein response and reducing diastolic blood pressure.

With respect to the GH analogs, claims 20 and 23 recite functional analogs. Accordingly, such claims are limited by common sense - if nothing else - to those analogs that achieve the desired results. See *In re Anderson*, 176 USPQ 331, 334 (CCPA 1973).

The rejection of claims 1, 2, 4, 5, 12 and 13 under 35 USC 112, second paragraph has been overcome by the newly presented method of use claims. Also, the claims no longer recite "preferably".

Claims 1, 2, 4, 5, 12 and 13 were rejected under 35 USC 102 as being anticipated by or under 35 USC 103 as being obvious over U.S. Patent 5,426,096 to Sonksen et al. In particular, Sonksen et al is concerned with using human growth hormone or a functional analog for treating hypoglycemia unawareness. Sonksen et al suggest administering high doses of growth hormone or a functional analog, which reduces insulin sensitivity and thereby reduces the risk of hypoglycemia. The problem of hypoglycemia unawareness occurs in some insulin-dependent diabetes patients (see col. 1, lines 58-61 and col. 2, lines 28-31).

Contrary to the suggestions in Sonksen et al, the present invention actually exhibits the reverse action of growth hormone or analogs thereof, which is unexpected and previously neither demonstrated nor suggested in the prior art. For example, according to an aspect of the present invention, administering growth hormone or an analog thereof to non-insulin dependent diabetes mellitus patients over a period of time, these patients became more sensitive to insulin. This increased insulin sensitivity tends to reduce the risk of these patients developing type 2 diabetes mellitus in the future.

Also, attached are copies of the figures that were inadvertently not included with the application. If the Examiner desires, such can be presented in verified form.

Since Sonksen et al do not disclose each and every limitation of the claimed invention, Sonksen et al do not anticipate the present invention. No claim recitation can be ignored in determining anticipation. See *Pac-Tex, Inc. v. Amerace Corp.*, 14 USPQ2d 187 (Fed. Cir. 1990). Anticipation requires the disclosure, in a prior art reference, of each and every recitation as set forth in the claims. See *Titanium Metals Corp. v. Banner*, 227 USPQ

773 (Fed. Cir. 1985), *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 1 USPQ2d 1081 (Fed. Cir. 1986), and *Akzo N.V. v. U.S. International Trade Commissioner*, 1 USPQ2d 1241 (Fed. Cir. 1986).

There must be no difference between the claimed invention and reference disclosure for an anticipation rejection under 35 USC 102. See *Scripps Clinic and Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001 (CAFC 1991) and *Studiengesellschaft Kohle GmbH v. Dart Industries*, 220 USPQ 841 (CAFC 1984).

Concerning the rejection under 35 USC 103, one must keep in mind that the properties of the subject matter and improvements which are inherent in the claimed subject matter and disclosed in the specification are to be considered when evaluating the question of obviousness under 35 USC 103. See *Gillette Co. v. S.C. Johnson & Son, Inc.*, 16 USPQ2d 1923 (Fed. Cir. 1990), *In re Antonie*, 195 USPQ 6 (CCPA 1977), *In re Estes*, 164 USPQ 519 (CCPA 1970), and *In re Papesch*, 137 USPQ 43 (CCPA 1963).

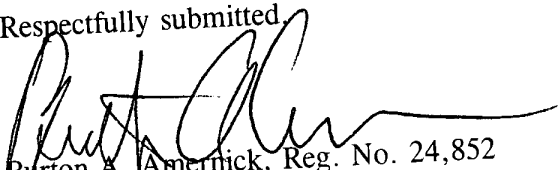
No property can be ignored in determining patentability and comparing the claimed invention to the prior art. Along these lines, see *In re Papesch*, supra, *In re Burt et al*, 148 USPQ 548 (CCPA 1966), *In re Ward*, 141 USPQ 227 (CCPA 1964), and *In re Cescon*, 177 USPQ 264 (CCPA 1973).

In view of the above, consideration and allowance are, therefore, respectfully solicited.

In the event that the Examiner believes an interview might serve to advance the prosecution of this application in any way, the undersigned attorney is available at the telephone number noted below.

The Commissioner is hereby authorized to charge any fees or credit any overpayment associated with this communication including any extension fees to Deposit Account No. 22-0185.

Respectfully submitted

A handwritten signature in dark ink, appearing to read 'Burton A. Amernick', with a long horizontal flourish extending to the right.

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